



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

*HFI-35 m3338n*

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

DEC 2 1999

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Michael Perez, President  
San Diego Products, Inc.  
1330 La Mirada Drive  
San Marcos, CA 92069

W/L 13-00

Dear Mr. Perez:

On October 18<sup>th</sup> and 20<sup>th</sup>, 1999, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of San Diego Products, Inc., located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products Regulation. By virtue of these deficiencies, the fisheries products processed at your facility are adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found the following deficiencies related to your dried shrimp product intended for immediate consumption:

1. Your firm has failed to prepare and implement a HACCP plan per 21 CFR §123.6 (b), although products being produced indicate the need for such a plan. A HACCP plan is needed for these products which would include critical control points such as proper labeling of allergenic ingredients.

The HACCP regulation 21 CFR §123.6 (a) requires that you perform a hazard analysis for each fish or fisheries product that you manufacture. When you identify one or more safety hazards associated with a product, 21 CFR §123.6 (b) requires that you have and implement a HACCP plan to control those hazards. 21 CFR §123.6 (c) details what a HACCP plan shall include.

2. Your firm has failed to monitor sanitation conditions and practices as required in 21 CFR §123.11 (b), and to document those findings with sanitation control records as required in 21 CFR §123.11 (c).

During the inspection, it was documented that your firm has no Sanitization Standard Operating Procedures (SSOPs) in place to control possible cross contamination sources. Residue from previous manufacturing operations involving possible allergens (tree nuts and legumes) was observed on food contact surfaces of equipment used to manufacture your dried shrimp product.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, which may include seizure and/or injunction.

We are very concerned that you have not yet implemented a HACCP plan for this product that addresses allergenic food additives, such as sulfites, as a critical control point. This deficiency is even more disturbing in light of the District's previous correspondence with your firm regarding HACCP deficiencies that included information regarding your product labeling and listing of allergenic ingredients, and the potential food safety hazard in multi-component foods these allergens pose.

We acknowledge your firm's written response to the Inspectional Observations noted on the Form FDA-483 issued during the current inspection. In light of your failure to make promised corrections after previous inspections, we have serious doubts about your commitment to making corrections and bringing your facility into compliance with all applicable laws and regulations. Because of the serious and repeat nature of the violations, and the possible significant health hazard associated with the manufacture of your dried shrimp product, we request that you contact this office to arrange a meeting with us to discuss this matter. You may contact the District Director's Office at 949-798-7714 to schedule this meeting.


Additionally, please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen days,

state the reason for the delay and the time within which corrections will be completed.

Your written reply should be directed to:

Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd, Suite 300  
Irvine, CA 92612-2445.

Sincerely,

  
Acting District Director  
Los Angeles District

cc: California Department of Health Services, Food & Drug Branch  
601 N. 7<sup>th</sup> Street  
Sacramento, California 94234-7320  
Attn: Stuart Richardson, Jr., Chief